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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/617,566 | 07/17/2000 | Samuel P. Sawan | SUR-004DVCN | 8355 |

21323 7590 06/06/2002

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[REDACTED] EXAMINER

LEVY, NEIL S

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1616 | |

DATE MAILED: 06/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.



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EXAMINER

ART UNIT

PAPER NUMBER

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 9/18/01

This action is FINAL.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

Claim(s) 25-49 is/are pending in the application.

Of the above, claim(s) 37-49 is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

Claim(s) 25-36 is/are rejected.

Claim(s) _____ is/are objected to.

Claims 25-49 are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119.

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of Reference Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

Applicant's election of group I, with catheter species in Paper No. 6 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 37-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 25-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: the base or surface on which the coating is—without the substrate, the coating must be free-standing—that does not seem to be the invention.

Claims 26-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"Derivatives" is indefinite. There is no antecedent basis for "surface" in claim 34.

Claim 33 compound is not known; typo?

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 34 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. One in the art would not be able to identify the means to provide in order to have microorganisms take up a part of the coating.

Claims 25-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claim is beyond the scope of the specification: it is seen how one could disperse within the matrices claimed an antimicrobial such that biocidal amounts would not be released; unless the antimicrobial coating was ineffective antimicrobial containing amounts of metals. How one can arrange no leaching, yet have a microbe take up the metal is not evident.

Applicant's claim 33 crosslinker is not identifiable in the CAS registry file—please provide IUPAC name and structure and component support.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) The invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5849311. Although the conflicting claims are not identical, they are not patentably distinct from each other because since the application claims are to a coating, it is met by the material of the patent.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA

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1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 25, 27, 28, 31, 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Murtfeldt-4592920.

The instant articles, catheters, are silver halide treated in a polyurethane coating (column 3, line 30-line 11, column 4) then crosslinked (cured with added bridging agent). No leaching occurs (column 6, lines 27-31).

Claims 25-28, 30-32, 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Fox Jr. et al 5019096.

Catheters (column 3, top) are coated with polyurethane's (column 4, A.) with incorporation of non-diffusing silver (column 9, lines 25-33). Silver forms include silver iodide, silver, silver oxide—with chlorhexidines (column 13, lines 35-58, column 14, top). Chlorhexidine can be construed to be a derivative of benzalkonium—thus, meets claim 26. crosslinked matrices are useable (column 5, 3.). the bacteria take up, the metal, as the invention is as the instant invention, and bacteria are killed, so the same functions follow the same articles, and effect thus claimed must be present.

Claims 25-27, 34 are rejected under 35 U.S.C. 102(a) as being anticipated by Honda et al JP 08176527.

Shown is a polymer, catatonic, with a metal, not leaching, as an antimicrobial coating. The polymer includes benzalkonium groups and derivatives.

Claims 25, 27, 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawamura et al JP 05033217.

Here, too Cu and the instant polymer coat articles, without metal leaching.

Claims 25-28, 31, 35 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Mermez et al '93.

See page 920; chlorhexidine-silver coated polyurethane catheters do not leach out antimicrobial; results show superior efficacy (page 921, 923).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 308-2412. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 305-4556 for regular communications and 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.

Levy:mv
June 4, 2002

NEIL S. LEVY
PRIMARY EXAMINER